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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,548

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Michael G. Lowery

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ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008



EXAMINER

LIN, JACK

ART UNIT

PAPER NUMBER

3768

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/763,548	Applicant(s) LOWERY ET AL.	
	Examiner Jack Lin	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/04 & 10/17/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on August 16, 2004 and October 17, 2005 are acknowledged. The references listed therein have been considered.
2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Page 3, line 24 – US Patent 6,002,952 is not listed on the IDS.

Specification

3. The disclosure is objected to because of the following informalities:

Page 1, line 31 – WO 2002/82989A1 should read WO 2002/082989A1.

Page 8, lines 4-9 – The applicant's definition of the phrase "concentration of an analyte" is different from that which is generally accepted in the art when values of hematocrit and level of blood pressure are included in the definition. The definition of "concentration of an analyte" as generally accepted in the art, not including values of hematocrit and level of blood pressure, will be used throughout the application.

Page 11, line 9 – "based on based on" should read "based on".

Page 15, line 32 – “user that user that” should read “user that”.

Appropriate correction is required.

Drawings

4. Regarding Figure 12, color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Objections

5. Claims 3 and 9 are objected to because of the following informalities:

With regard to Claim 3, “at one” (line 4) should read “at least one”.

With regard to Claim 9, a consistent phrase is not used to refer to claim elements. Claim 9 uses the phrase “the data” whereas other claims use the phrase “the optical data.”

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 4, 9, and 13 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention.

Regarding Claim 4, in view of the objection detailed in paragraph 1 above, Claim 4 fails to correspond in scope with that which applicants regard as the invention because the determination of blood pressure is not a determination of a concentration of an analyte.

Regarding Claim 9, it does not clearly state what is further limited to provide that the data is independent of the cardiac pulse. It is unclear whether the claim is further limiting the collecting step to certain time periods, requiring certain durations for the measurement, or other limitations that would limit the data as being independent of the cardiac pulse.

Regarding Claim 13, it recites the limitation "the data points" in line 29. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 1, 3-10, and 13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

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Claim 1 specifies a method to collect optical data and to identify artifacts in the data. However, claim 1 does not specifically or inherently produce tangible results from the claimed method steps. Claims 3-10 and 13 further limit claim 1 but also do not specifically or inherently produce tangible results from the method steps.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 5-9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hall (US 4,955,379). Hall discloses a motion artifact detector system (col. 3, lines 12-15) that can be incorporated into a pulse oximeter (col. 1, line 7) to identify and filter artifact signals (col. 1, line 8 and col. 2, lines 31-47) using an algorithm (figure 5).

Regarding Claim 5, the optical data can be used to calculate saturation of oxygen in the blood (col. 1, line 11).

Regarding Claims 6-7, light in the wavelengths of 660 nm and 940 nm are used (col. 1, line 25).

Regarding Claims 8 and 10, a pulse oximeter measures the light signals as a function of real time (Figure 4).

Regarding Claim 9, the current understanding of Claim 9 in view of the 35 U.S.C. 112, second paragraph rejection (see paragraph 7 above) is anticipated by Hall. An oximeter can

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collect data over a period of time that is independent of the cardiac pulse and it can collect data within the time period of a cardiac pulse to make the data independent of the cardiac pulse.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall as applied to Claim 1 above, and further in view of Ukawa et al. (US 5,485,838). Hall teaches all the features of the claimed invention except that the processed signals can be obtained from reflectance measurements or can be used to determine blood pressure. Ukawa et al. shows these features to be old in the physiological monitoring art.

Regarding Claim 3, Ukawa et al. teaches optical data can be acquired by propagating energy into the tissue and measuring the amount of light reflected (col. 2, lines 44-49). It would

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have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teachings of Ukawa et al. to modify the method of Hall to also acquire optical data through reflectance measurements in order to have an alternative to collecting optical data through transmission measurements.

Regarding Claims 4, Ukawa et al. teaches a non-invasive blood pressure measuring device (col. 1, lines 7-8) that uses photoelectric plethymograph signals to measure blood pressure (col. 1, lines 29-32). It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teachings of Ukawa et al. to modify the method of identifying motion artifacts of Hall into a physiological monitor that determines blood pressure in order to have a monitoring system that can monitor different physiological properties in addition to oxygen saturation.

15. Claims 2, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall as applied to Claim 1 above, and further in view of Pologe et al. (US 5,766,127). Hall discloses applicants' basic inventive concept, a method to identify motion artifacts in optical measurements, substantially as claimed with the exception of providing a signal to indicate the occurrence of an artifact. Pologe et al. shows this feature to be old in the physiological monitoring art (Figure 6). It would have been obvious to one of ordinary skill in the art at the time of applicants' invention from the teaching of Prologe et al. to modify the method of identifying motion artifacts in optical measurements of Hall by adding the alert feature of Pologe et al. in order to alert the operator of an occurrence of an artifact.

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Conclusion


16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Diab et al. (US 6,501,975 B2) teaches a signal processor that can be incorporated into a number of physiological monitors to identify and remove artifact noise, such as artifacts caused by movement, using an algorithm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jack Lin
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ERIC F. WINAKUR
PRIMARY EXAMINER